## DETAILED ACTION

Claims 1-28 and 35 are pending, claims 29-34 are cancelled, and claims 1, 11, 23, and 35 are currently amended.

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/14/2008 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. **Claims 1, 2, 4-12, 14-28, and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (US 2001/0049547 A1) in view of Acosta et al. (US 7,182,779 B2).

With regard to **claims 1, 4, 5, and 11**, Moore discloses a pusher assembly (see entire document) comprising a catheter (11), a first tubular portion (13) and a second tubular portion (12). The first tubular portion is comprised of non-rigid polymer ([0014]). The second tubular portion extends distally from the first tubular portion and, as shown in Figure 1, comprises a flexible section and a stent carrying section ([0014]). A pusher member (14) is located proximal of the stent on the second tubular portion and urges the stent from the catheter ([0015]). The pusher member comprises a polymer and has a proximal taper ([0015]; Figure 1). Furthermore, the pusher member is inherently adapted to be positioned at an acute bend in a patient's body and absorb preload pressure form the stent. As shown in Figure 1, the outside diameter of the first tubular portion (13) is less than the inside diameter of the catheter (11).

Although Moore teaches the pusher member comprises a polymer, Moore does not specifically teach the pusher member as configured to conform to a distal end of the stent.

Acosta et al. (hereinafter Acosta) also discloses a pusher member (90) that engages the proximal end of the stent to urge the stent from the catheter (column 13, lines 23-43). The pusher member comprises a polymer, specifically PTFE (column 13, lines 39-40). Since Acosta teaches that pusher members comprised of PTFE are well

known in the art and sufficient to urge a stent from a catheter, it would have been obvious for Moore to use PTFE for the polymeric pusher member. Therefore the pusher member would be configured to conform to a distal end of the stent and reduce the likelihood of partial deployment.

With regard to **claims 2 and 12**, the flexible section of the second tubular portion has a preselected length depending on the application ([0016]). The region comprising the greatest likelihood of a kink intrinsically corresponds to the region of greatest flexibility.

With regard to **claims 6 and 18**, as shown in Figures 1 and 5, the second tubular member has a smaller outer diameter than the first tubular portion.

With regard to **claims 7-9, 19-21, and 24-26**, the second tubular portion is further disclosed as comprising a braided polyimide tubing ([0014]).

With regard to **claims 10 and 22**, the stent carrying section and the flexible section are comprised of a single continuous element ([0014]). The sent is positioned along the sent carrying section between the pusher member (14) and a tapered distal tip (16).

With regard to **claim 14**, as shown in Figure 1, the proximal end of the stent is received by the pusher member and inherently absorbs preload pressure.

With regard to **claims 15 and 23**, as shown in Figure 1, the pusher member (14) comprises a face and a proximal taper. Additionally, as shown in Figure 5, the second tubular portion comprises a thinner wall than the first tubular portion.

With regard to **claims 16 and 28**, the stent is self-expanding ([0012]).

With regard to **claim 17**, as shown in Figure 1, the pusher assembly and stent are slideably disposed in the catheter (11).

With regard to **claim 27**, the stent carrying section is distal of the flexible section and extends to the distal tip.

With regard to **claim 35**, as shown in Figure 5, the second tubular portion extends the entire length of the first tubular portion ([0016]).

5. **Claims 1-5 and 6-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft (US 5,702,418) in view of Wilson et al. (US 6,425,898 B1) and Acosta (US 7,182,779 B2).

With regard to **claims 1, 4, 5, and 11**, Ravenscroft discloses a pusher assembly of a stent delivery system (see entire document) comprising a catheter (11), a first tubular portion (15 or 16), and a second tubular portion (17). The first tubular portion comprises PEBAX or is disclosed as flexible, which clearly overlaps the instantly claimed non-rigid polymer (column 5, lines 23-26. 29-30). As shown in Figures 5, 1, and 4, the second tubular portion comprises a distal stent carrying section and a proximal section, located proximal of the stent carrying section. The second tubular (17) is disclosed as flexible so that the proximal section clearly overlaps the instantly claimed flexible section. Furthermore, it is the examiner's position that the second tubular portion distally extends from the first tubular portion, as shown in Figure 5. Additionally, the outside diameter of the first tubular portion (15 or 16) is less than the inside diameter of the catheter (11) (Figure 5).

Ravenscroft further discloses rings (23) placed around the stent to urge the stent distally when advanced form the catheter. However, Ravenscroft does not specifically disclose a soft pusher member having a tapered proximal surface to urge the stent distally.

Wilson et al. (hereinafter Wilson), as shown in Figure 5, discloses a catheter assembly comprising a distal stent carrying section. Immediately proximal to the stent carrying section is pusher member (21 and 22). Wilson teaches that the pusher member contacts the stent and helps to urge the stent out of the sheath when deployed into the patient at the target site (column 5, lines 58 through column 6, line 21). The pusher member is further disclosed as made from any material known in the art which encompasses polymer materials. As shown in Figure 5, the pusher member (21 and 22) tapers proximally and is intrinsically configured to be positioned at an acute bend in a patient's body and absorb preload pressure.

If Applicant were to argue that the taper of the pusher member is not gradual, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the pusher member. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Wilson teaches that the pusher member advantageously pushes the stent during deployment while preventing the stent from proximally retracting (column 6, lines 2-6). Therefore, since Ravenscroft discloses a pusher member and Wilson discloses a

specific pusher member that is advantageous, it would have been obvious to one of ordinary skill in the art at the time of the invention for Ravenscroft to utilize the pusher member of Wilson.

However, Wilson does not specifically disclose the pusher member as comprised of PTFE. Acosta also discloses a pusher member (90) that engages the proximal end of the stent to urge the stent from the catheter (column 13, lines 23-43). The pusher member comprises a polymer, specifically PTFE (column 13, lines 39-40). Since Acosta teaches that pusher members comprised of PTFE are well known in the art and sufficient to urge a stent from a catheter, it would have been obvious for Ravenscroft in view of Wilson to use PTFE for the polymeric pusher member. Therefore the pusher member would be configured to conform to a distal end of the stent and reduce the likelihood of partial deployment.

With regard to **claims 2 and 12**, Ravenscroft teaches the pusher assembly is utilized for endoscopic delivery of stent to a patient (column 1, lines 6-9). Therefore, it would have been obvious to one of ordinary skill in the art for each component, specifically the flexible section, to comprise a preselected length that is proper for the designated procedure. The region comprising the greatest likelihood of a kink intrinsically corresponds to the region of greatest flexibility.

With regard to **claims 3 and 13**, the pusher member of Wilson is further disclosed as comprising a radiopaque filler (column 6, lines 19-21).

With regard to **claims 6 and 18**, as shown in Figure 5 of Ravenscroft, the second tubular portion (17) comprises a smaller outer diameter than the first tubular portion (15 or 16).

Withy regard to **claims 7-9, 19-21, and 24-26**, Ravenscroft does not specifically disclose the second tubular member as comprising a metal-reinforced polymer material or as Nitinol. Wilson teaches the distal end of the tubular shaft (10) comprises a polymer material reinforced with metal braided wires or Nitinol (column 5, lines 27-35). This gives the tubular member shaft the necessary flexibility and strength to navigate vessels and deploy the stent (column 5, lines 38-44). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the distal end of the tubular member, the second tubular member, to comprise a polymer reinforced with metal ort Nitinol, a nickel-titanium alloy

With regard to **claims 10 and 22**, as shown in Figure 5 of Ravenscroft, the stent carrying section and the flexible section are comprised of a single continuous element. The sent is positioned along the sent carrying section between the soft pusher member and a tapered distal tip (13).

With regard to **claim 14**, Ravenscroft in view of Wilson would produce a pusher assembly wherein the proximal end of the stent is received by the pusher member and intrinsically absorbs preload pressure.

With regard to **claims 15 and 23**, as shown in Figure 4 of Wilson, the pusher member (22 and 21) comprises a face, the distal portion of 22, which has a diameter equal to the preloaded stent. Ravenscroft teaches the second tubular portion as thin

and the first tubular portion as thick (column 5, lines 3-6). Therefore, the second tubular portion has a thinner wall than the first tubular portion.

With regard to **claims 16 and 28**, Ravenscroft further discloses the stent as self-expanding (column 4, lines 60-62).

With regard to **claim 17**, as shown in Figures 5, 1, and 4 of Ravenscroft, the pusher assembly and stent are slideably disposed in the catheter (11).

With regard to **claim 27**, the stent carrying section of Ravenscroft is distal of the flexible section and extends to the distal tip.

6. **Claims 3 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (US 2001/0049547 A1) in view of Acosta (US 7,182779 B2) as applied to claims 1 and 11, and further in view of Wilson (US 6,425,898 B1).

Moore in view of Acosta disclose the invention substantially as claimed but fails to teach the pusher member comprising a radiopaque filler.

Wilson also discloses a push member to urge the stent from the catheter. The pusher member comprises a radiopaque filler to aid in positioning the stent at the target site (column 6, lines 19-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the pusher member of Moore to also comprise a radiopaque filler for the advantage disclosed by Wilson.

7. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft (US 5,702,418) in view of Wilson (US 6,425,898 B1), Acosta (US 7,182,779 B2), and Chew (US 2004/0215331 A1).

Ravenscroft in view of Wilson and Acosta discloses the invention substantially as claimed but fails to teach the second tubular member (17) as extending along the entire length of the first tubular member (15 or 16).

Chew discloses a catheter with multiple tubular members. As shown in Figure 20, an inner tubular member (336) extends the length of middle tubular member (334) which extends the length of outer tubular member (332) ([0132]). Inner tubular member forms a guidewire lumen ([0132]). Since Ravenscroft also discloses a guidewire and multiple tubular members, it would have been obvious to one of ordinary skill in the art at the time of the invention for the second tubular portion (equivalent to an inner tubular member) to extend the length of the first tubular portion (equivalent to a middle tubular member) and form a guidewire lumen.

***Response to Arguments***

8. Applicant's arguments filed 08/14/2008 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that Wilson does not disclose a tapered pusher member.

With respect to argument (A), the pusher member of Wilson comprises members 21 and 22. As shown in Figure 5, the members become smaller in diameter from the

distal to proximal end. Therefore, the pusher member diminishes and becomes progressively smaller. This diminish is gradual since member 21 is only slightly smaller than member 22. However, it Applicant were to continue to argue that the pusher member is not tapered gradually, this limitation is an obvious design choice.

9. Applicant's arguments with respect to the rejection of Moore have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/20/2008
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